

AUG 16 2002

KD11700



### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of Karl Storz Endoscopy - America's knowledge.

**Applicant:**

Karl Storz Endoscopy – America, Inc.  
on behalf of:

Karl Storz Lithotripsy-America, Inc.  
1765 The Exchange, Suite 100  
Atlanta, GA 30339  
(770) 303-0808

**Contact:**

Jennifer S. Portugal  
Clinical Affairs Specialist

**Device Identification:**

Common Name

Lithotripters

Trade Name

Modulith® Lithotripter Model SLK

**Indication:** The Storz Modulith® Lithotripter Models SLK is manufactured by Storz Medical AG are indicated for the therapeutic use in the treatment of ureteric calculi in lithotripsy procedures.

**Device Description:** The lithotripter models described in this submission are intended for use by qualified surgeons during a variety of lithotripsy surgical procedures.

**Substantial Equivalence:** The proposed labeling changes to the Storz Modulith® Lithotripter Models SLK have no effect on the safety and effectiveness of the device's intended use.

Signed:

Jennifer Portugal  
Clinical Affairs Specialist



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 16 2002

James A. Lee, Ph.D.  
Senior Regulatory Affairs Specialist  
Karl Storz  
Endoscopy-America, Inc.  
600 Corporate Pointe 5<sup>th</sup> Floor  
CULVER CITY CA 90230-7600

Re: K011700  
Trade/Device Name: Storz Modulith® Lithotripter  
Model SLK with Inline  
Ultrasound Imaging  
Regulation Number: 21 CFR 876.5990  
Regulation Name: Extracorporeal shock wave  
lithotripters, urological  
Regulatory Class: II  
Product Code: 78 LNS  
Dated: May 17, 2002  
Received: May 20, 2002

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

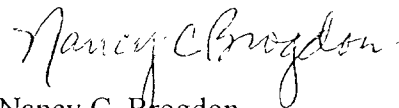
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K011700

Device Name: Modulith® Lithotripter Model SLK

Indications for Use: Storz Modulith® Lithotripter Model SLK is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

David A. Depina  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K011700

(Optional Format 1-2-96)